Claims 3, 7, and 17-18 stand rejected under 35 U.S.C. § 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Claims 3, 7, and 17 have been amended to cure the rejections under 35 U.S.C. §112. With respect to Claim 18, no reason was given for the rejection under 35 U.S.C. § 112. Applicants assume this rejection was caused by the dependency of Claim 18 from Claim 17. Since Claim 17 has been amended to overcome the rejection under 35 U.S.C. § 112, Claim 18 is now believed to be in condition for allowance.

Claims 1-5, 7, 11-13, and 17-20 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Brisken et al. (U.S. Patent No. 5,846,218). Brisken et al. teach a catheter system with two tubular transducers disposed on the proximal and distal sides of a flange in the middle of a tubular holder (col. 9, lines 18-21). Brisken et al. fail to teach "**a low density material contained in the gap** for reflecting the energy from the gap toward the body tissue target area," as recited by amended Claim 1. Brisken et al. fail to teach an enclosed gap which contains the claimed substance. Accordingly, Claim 1 is patentably allowable over Brisken et al. and allowance of the claim is respectfully requested. Claims 3-5, 7, and 11 depend from Claim 1 and are accordingly allowable for the same reason. Claim 2 has been canceled.

With respect to Claim 12, i.e., the next independent claim, Brisken et al. fail to teach "the distal end of a transducer...positioned at a distance from the proximal end of an adjacent transducer **to allow the catheter to bend in the area between the pair of adjacent transducers**," as recited by Claim 12. Allowance of Claim 12 is, therefore, requested. Claim 13 depends from Claim 12 and is accordingly allowable for the same reason.

With respect to Claim 17, i.e., the next independent claim, Brisken et al. fail to teach a "gap having a low density material for reflecting the energy from the gap towards the target

area," as recited by Claim 17. Allowance of Claim 17 is, therefore, requested. Claim 18 depends from Claim 17 and is accordingly allowable for the same reason.

With respect to Claim 19, i.e., the next independent claim, Brisken et al. fail to teach "the electronic signal...**oscillated approximately equal to the mechanical resonance frequency of the transducer,**" as recited by Claim 19. Allowance of Claim 19 is, therefore, requested. Claim 20 depends from Claim 19 and is accordingly allowable for the same reason.

Claims 21-33 have been added and are supported by the original disclosure. No new matter has been added. Allowance of Claims 21-33 is respectfully requested.

CONCLUSION

Pending Claims 1, 3-5, 7, 11-13, and 17-33 are allowable and allowance of the application is hereby solicited. If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415)954-0323.

Date: March 13, 2002

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the Commissioner for Patents, Attn.: Box Issue Fee, Washington, D.C. 20231, on December 20, 2001.

Date: _____ By: _____
Tracie Glowner

APPENDIX A

Version With Markings To Show Changes Made

In the Specification:

Attached hereto is "Appendix B," a marked-up version of the substitute specification to show the changes made, and "Appendix C" an un-marked version of the substitute specification. Marked-up amended drawings are filed in a separate paper in accordance with 37 C.F.R. § 1.121.

In the Claims:

Please amend Claims 1, 3-5, 7, 11-13, and 17-20 as follows:

1. (Once Amended) A medical assembly for local delivery of ~~at least one~~ a therapeutic substance to an internal body tissue target area comprising:

(a) a catheter having a distal end and a proximal end;

(b) a delivery lumen ~~on said catheter, said lumen~~ extending from the distal end of the catheter to the proximal end of the catheter for the delivery of a therapeutic substance ~~thereon through~~; ~~and~~

(c) a first transducer, for creating an energy, supported ~~by~~ at ~~least a portion of~~ the distal end of the catheter ~~assembly, said first transducer being supported by said catheter distal end at~~ by a ~~preselected~~ number of anchoring points, wherein an inner surface of the transducer is positioned at a ~~controlled and preselected~~ distance from an outer surface of the catheter, wherein

~~said~~ the distance defines a gap between ~~said~~ the outer surface of the catheter and ~~said~~ the inner surface of the transducer; and

(d) a low density material contained in the gap for reflecting the energy from the gap toward the body tissue target area.

2. Please cancel Claim 2 without prejudice.

3. (Once Amended) The medical assembly of Claim ~~2~~ 1, wherein ~~said~~ the low density material is selected from the group consisting of ambient air, oxygen, nitrogen, helium, open-cell polymer foam, closed-cell polymer foam and mixtures thereof.

4. (Once Amended) The medical assembly of Claim 1, wherein ~~said~~ the transducer ~~is~~ comprises a hollow tubular shaped body, and wherein the catheter is extended through the hollow body.

5. (Once Amended) The medical assembly of Claim 1, wherein ~~said~~ the distance is greater than about 25 μm in length.

6. Please cancel Claim 6 without prejudice.

7. (Once Amended) The medical assembly of Claim 1, wherein the ~~said at least one~~ therapeutic substance is selected from a group consisting of ~~including~~ antineoplastic, antiinflammatory, antiplatelet, anticoagulants, fibrinolytic, thrombin inhibitor, antimitotic, and antiproliferative substances and mixtures thereof.

8.–10. Please cancel Claims 8-10 without prejudice.

11. (Once Amended) The medical device assembly of Claim 1, further comprising:

a second transducer supported by ~~at least a portion of~~ the distal end of the catheter assembly, each transducer having a proximal end and a distal end, wherein the distal end of ~~said~~ the first transducer is positioned at a ~~preselected~~ distance from the proximal end of ~~said~~ the second transducer.

12. (Once Amended) A medical assembly for local delivery of a therapeutic substance to an internal body tissue target area comprising:

(a) a catheter having a distal end and a proximal end;

(b) a delivery lumen ~~on said catheter, said lumen~~ extending from the distal end of the catheter to the proximal end of the catheter for the delivery of a therapeutic substance ~~therethrough~~; and

(c) a plurality of transducers supported ~~by~~ at ~~least a portion of~~ the distal end of the catheter ~~assembly~~, each transducer having a proximal end and a distal end, wherein the distal end of a transducer is positioned at a ~~preselected~~ distance from the proximal end of an adjacent transducer to allow the catheter to bend in the area between the pair of adjacent transducers.

13. (Once Amended) The medical assembly of Claim ~~11~~ 12, wherein each of ~~said~~ the plurality of transducers are supported by ~~said~~ the catheter ~~distal end at~~ by a ~~preselected~~ number of anchoring points, wherein an inner surface of each transducer is positioned at a ~~preselected~~ distance from an outer surface of the catheter, wherein ~~said~~ the distance defines a gap between ~~said~~ the outer surface of the catheter and ~~said~~ the inner surface of the transducer.

14.-16. Please cancel claims 14-16 without prejudice.

17. (Once Amended) A method for delivering a therapeutic substance to an internal body tissue target area comprising the acts of:

(a) providing a catheter having a distal end and a proximal end, and further having a delivery lumen, said delivery lumen extending from the distal end of the catheter to the proximal end of the catheter for delivery of a therapeutic substance ~~therethrough~~;

(b) further providing a transducer, for creating an energy, supported ~~by~~ at ~~least a portion of~~ the distal end of the catheter ~~assembly, said transducer being supported by said distal~~

~~end at~~ by a ~~preselected~~ number of anchoring points, wherein an inner surface of the transducer is positioned at a ~~preselected~~ distance from an outer surface of the catheter, ~~wherein said~~ the distance ~~defines~~ defining a gap between ~~said~~ the outer surface of the catheter and ~~said~~ the inner surface of the transducer, the gap containing a low density material for reflecting the energy from the gap towards the target area;

(c) positioning said catheter proximate ~~said~~ the internal body tissue target area;

(d) causing a therapeutic substance to elute from ~~said~~ the delivery lumen at the distal end of the catheter; and

(e) transmitting an electrical signal to ~~said~~ the transducer for creating the energy.

18. (Once Amended) The method of Claim 17, wherein ~~said~~ the therapeutic substance is selected from a group ~~including~~ consisting of antineoplastic, antiinflammatory, antiplatelet, anticoagulants, fibrinolytic, thrombin inhibitor, antimitotic, and antiproliferative substances and mixtures thereof.

19. (Once Amended) A method of treating an internal body tissue with a therapeutic substance comprising:

(a) locally delivering the therapeutic substance in the vicinity of the internal body tissue;

(b) generating ultrasonic energy in the vicinity of the internal body tissue, wherein the ultrasonic energy is generated by a transducer; ~~transporting the therapeutic substance, penetrating into the internal body tissue via the ultrasonic energy;~~ and

(c) ~~amplifying~~ adjusting the ~~applied~~ ultrasonic energy by manipulating an electronic signal ~~driving the ultrasonic energy generation~~ applied to the transducer, wherein the electronic signal is oscillated approximately equal to the mechanical resonance frequency of the transducer.

20. (Once Amended) A method according to Claim 19, further comprising:

amplifying the ~~applied~~ ultrasonic energy by interposing a gap between a catheter for delivering the therapeutic substance and a the transducer for generating the ultrasonic energy.

Please add Claims 21-33 as follows:

-- 21. The method of Claim 17, wherein the electrical signal has a frequency greater than about 20 kHz.

22. The method of Claim 17, wherein the electrical signal has a voltage greater than about 94.8 V.

23. The method of Claim 19, wherein the electrical signal has a frequency greater than about 20 kHz.

24. The method of Claim 19, wherein the electrical signal has a voltage greater than about 94.8 V.

25. A medical device comprising:

a lumen for inserting in a body passageway; and

a first transducer supported by the lumen, the first transducer having a first end and a second end;

a second transducer supported by the lumen, the second transducer having a first end and a second end, wherein the first end of the second transducer is positioned at a distance from the second end of the first transducer so as to allow the lumen to be flexible in the area between the second end of the first transducer and the first end of the second transducer.

26. The medical device of Claim 25, additionally including an enclosed gap region located between the first transducer and the lumen, the enclosed gap region containing a substance.

27. The medical device of Claim 26, wherein the substance is selected from a group consisting of ambient air, oxygen, nitrogen, helium, open-cell polymer foam, closed-cell polymer foam and mixtures thereof.

28. A medical device comprising:

a transducer for emitting an energy, the transducer having a hollow body;

a lumen disposed through the hollow body, wherein a first region and a second region of the hollow body are sealed against the lumen to create an enclosed space region; and

a substance contained in the enclosed space region for directing the energy transmitted from the transducer away from the lumen.

29. The medical device of Claim 28, wherein the transducer is a piezoelectric crystal.

30. The medical device of Claim 28, wherein the substance is selected from a group consisting of ambient air, oxygen, nitrogen, helium, open-cell polymer foam, closed-cell polymer foam and mixtures thereof.

31. The medical device of Claim 28, wherein the lumen is part of a catheter assembly.

32. The medical device of Claim 13, additionally including a substance contained in the gap.

33. The medical device of Claim 13, additionally including a low density material contained in the gap. --